UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

January 22, 2021

MEMORANDUM

Subject: **Revised** Efficacy Review for Fabric Treated with Livinguard Technology, EPA File No. 95700-E; DB Barcode: D459604; Submission #: 1054331; E-Sub #: 52336

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Date Signed: December 9, 2020

To: John Hebert, Acting RM 33 / Zebora Johnson
Regulatory Management Branch I
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Applicant: Livinguard, AG
Bahnhofstrasse 12
6300 Zug, Switzerland
c/o: KRK Consulting

Formulation from the Label:

Active Ingredient	% by wt.
Silver Ions	0.18 %
Polyhexamethane Biguanide	0.26 %
Propiconazole	0.44 %
3-(Trimethoxysilyl) Propyldimethyloctadecyl ammonium chloride	0.65 %
Other Ingredients	98.47 %
Total	100.00 %

I. BACKGROUND

Product Description (as packaged, as applied): Treated Fabric

Submission type: New end use product

Currently registered efficacy claim(s): NA

Requested action(s): Review of new data

Documents considered in this review:

- Letter from applicant representative to EPA dated 02/28/2020
- Confidential Statement of Formula (EPA Form 8570-4) dated 01/21/2021
- Certification with Respect to Citation of Data (EPA Form 8570-34) dated 02/27/2020
- Data Matrix (EPA Form 8570-35) dated 02/27/2020
- Revised Certification of Analysis Lots 6-8 (on 01/21/2021) but dated 12/10/2016
- One efficacy study (MRID no. 51206114 and 51206109)
- Proposed label dated 01/21/2021

II. PROPOSED USE DIRECTIONS

Washing Instructions:
● Do not use Bleach – bleach will adversely affect Livinguard® durability and effectiveness.
● Use Non-Ionic Detergent.
● Rinse with Citric Acid to remove any residual soap or detergent.
● Washing, Drying and Ironing – not to exceed 160°F as recommended by fiber content of fabric to prevent shrinkage.

Product Label
Fabric is guaranteed to be effective in reducing Staphylococcus aureus ATCC 6538
Pseudomonas aeruginosa ATCC 15442 if product is washed after 48 hours of use. Product has been tested up to a total of 30 washings. The use of this product is a supplement to and not a substitute for standard infection control practices: user must continue to follow all current infection control practices, including regular washes and good hygiene practices. Textile materials were tested in fabric form. Antimicrobial treated textile has been shown to reduce microbial contamination, but does not necessarily prevent cross contamination.
Washed _____ Times

III. DESCRIPTION OF THE EFFICACY DATA

1. MRID 512061-14, "Antimicrobial efficacy of Treated Fabric with Livinguard Technology". Organisms: *Pseudomonas aeruginosa* (ATCC 15442) and *Staphylococcus aureus* (ATCC 6538)", for Treated Fabric with "Livinguard Technology"; by Absar Alum, Ph.D. Study conducted at BioDetek Laboratory; Study completion date - December 15, 2017. Project No. HPX-1.

Tested Fabric: Peached white fabric blind 65%polyester and 35% cotton twill fabric
Fabric Lot Numbers: L6E6-U L7E7-U; and L8E8-U: Unlaundered and 30 time Laundered or washed
Unlaundered Fabric Treated with Livinguard Technology: L6E6-T; L7E7-T; and L8E8-T
Treated Fabric Lot Numbers L6E6-TW; L7E7-TW; and L8E8-TW: 30 time Laundered or washed
The fabric treatment rate is 98.9 gallons of solution per 694 lbs fabric.

The percentage weight of active ingredients added to the test fabrics before washing is 1.38% (1.38lbs/100 lbs treated fabric)

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442) and *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. L6E6-TW; L7E7-TW; and L8E8-TW) of Treated Fabric (65%polyester and 35% cotton twill fabric) with Livinguard Technology, were tested according to EPA Approved Protocol 90072PA4 (copy provided). The product was received ready-to-use spray. Testing was conducted in triplicates samples per product lot and per organism. The fabric coupons were washed 30 times as specified in the protocol. Briefly, the coupons were subjected to 30 wash cycles, each cycle consisted, 1) laundry washing (85±15ºC) by adding 5 drops of non-ionic detergent, Tergitol NP 40, followed by rinse cycle; 2) drying for 20 minutes (75±10ºC); 3) ironing for 30 second; 4) incubation for 2hour at 36±2ºC / 85-95% relative humidity; 5) UV exposure for 15±2 minutes at 20-25ºC; 6) inoculation with 0.1ml of test culture yielding ~2×10^4 CFUs per coupon. The last cycle (30th wash cycle) was performed without detergent and after UV exposure stored in zip lock bag at ambient temperature (25±5ºC). Just before efficacy test coupons were washed without detergent and rinsed in 0.03% citric acid. Samples were subjected to 12 inoculations within 24 hours, followed by bacterial recovery and analyses using pour plate method. The analyses were completed within 48 hours. Carriers were inoculated initially with 2.0×106 cfu per coupon, followed by eleven inoculations of 1.5×10^4 cfu per coupon within 24 hours at 2 hours intervals; and finally inoculated with 1.5×10^8 cfu per coupon. After10 minute contact time each coupon was neutralized by added to a test containing 5 glass beads and 20ml of neutralization broth (Casein peptone lecithin polysorbate broth). The test tubes (containing test coupon, glass beads and neutralization broth) were vortexed for 30 sec to recover the inoculated bacteria from fabric. Recovered samples were serially diluted and assayed using pour plate technique. Plates were incubated at 36±2ºC for 48 hours and bacterial colonies were counted, and data are reported. Controls included untreated unwashed carriers, untreated 30 times washed carrier, unwashed treated carriers, sterility, purity, viability, and neutralization.

PROTOCOL AMMENDMENTS

- Addition of citric acid solution to the rinse cycle to assist in the removal of the detergent. This being a very common practice in commercial laundering.
- Ironing of fabric for 30 seconds which is also a common practice in commercial laundering.
- Efficacy testing conducted without abrasion between re inoculations, as it has been noticed that abrasion does not make any significant impact on the efficacy testing.

PROTOCOL DEVIATIONS

- During the washing steps coupons were incubated at temperature and relative humidity specified in the protocol version 1. (Temperature: 36±2ºC, and RH 85-95%)
- The Unlaundered Treated Textile was extremely hydrophobic, therefore, during the non-continuous reduction test, contact time was considered after complete adsorption of inoculum in the test coupons

IV. STUDY RESULTS

MRID # 512061-14	Organism	Lot No.	Log_{10} Average Survivors	Average Log_{10} Reduction	Laundered Control (Average Log_{10})
65% polyester and 35% cotton twill fabric blend	*Staphylococcus aureus* (ATCC 6538)	L6E6-TW	3.081	5.155	8.091
		L7E7-TW	3.087	5.146	8.046
		L8E8-TW	3.08	5.152	8.077
	Pseudomonas aeruginosa (ATCC 15442)	L6E6-TW	3.07	5.124	8.088
		L7E7-TW	3.12	5.117	8.046
		L8E8-TW	3.127	5.122	8.080

V. CONCLUSIONS

MRID #	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data Support Label Claims?
512061-14	**Residual Self Disinfection Bactericidal**	Fabric surfaces	Fabric RTU	10 minutes	5% FBS	NA	*Staphylococcus aureus* (ATCC 6538) *Pseudomonas aeruginosa* (ATCC 15442)	**Yes if fabric treatment rate and addon weight are indicated**
512061-09	**Fabric Types**	65% polyester 35% cotton	-	-	-	-	-	**100% Cotton. 100% Viscose. All viscose or cotton fabric blends containing a maximum of 65% Polyester.**

VI. LABEL COMMENTS

1. Use of fabric blend 65% polyester 35% cotton as the worst case absorption material to be used for efficacy studies is acceptable to support:

- 100% viscose fabric
- 100% cotton fabric
- All polyester-viscose fabric blends with maximum 65% polyester
- All polyester-cotton fabric blends with maximum 65% polyester

2. The proposed label claims **are acceptable** regarding the use of the product, Fabric Treated with Livingard Technology (EPA File No. 95700-E), as an effective continuous residual self-disinfectant, against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442), on visibly clean treated fabric surfaces, at room temperature, for a 10-minute contact time.

Registrant must indicate on the label the following:

- **Fabric treatment rate in volume of product per weight of treated fabric - at least 14.3 gallons per 100 lbs of fabric.**
- **To be effective, the percentage weight of active ingredients added to the test fabrics before washing must be at least 1.38% (1.38lbs/100 lbs treated fabric – using dried weight of fabric, before and after treatment)**
- **Residual self-disinfection must be up to 24 hours.**

2. The following labeling considerations should be taken into account:

- On page 1 of the proposed label, change “Other Ingredients” percentage and revise percentage of “3-(Trimethoxysilyl) Propyldimethyloctadecyl ammonium chloride” in asterisk note.
- Note that per efficacy testing, the product will be limited to a minimum 10-minute contact time with continuous activity for up to 24 hours. Claims of kill in less than 10 minutes and duration for over 24-hours will not be acceptable.
    - Edit statement to read “Effective after 12 repeated inoculations of bacteria **within 24 hours**”.
    - Change all 48 hours continuous self-disinfection claims to 24 hours.
- Add washing instructions, number of industrial washes to the “Product Label”

- Add fabric treatment rate (at least 14.3 gallons per 100 lbs of fabric) and instructions to the “Product Label”
- Add minimum addon 1.38% weight for effectiveness (at least 1.38lbs/100 lbs treated fabric – using dried weight of fabric, before and after treatment) to the “Product Label”.